K013527

3. Summary of Safety and Effectiveness Information:

DEC 21 2001

510(k) SUMMARY

Submitter:	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact:	Bonnie Smith (610) 647-9700
Name of the Device:	Synthes (USA) Reamer Irrigator Aspirator (RIA) System
Classification:	Class II, 21 CFR 888.4540 and 888.1100
Common or Usual Name:	Orthopedic manual surgical instrument; Arthroscope
Predicate (unmodified) Device:	Synthes (USA) Reamer Irrigator Aspirator (RIA) System, K993335
Device Description:	Synthes RIA System is a flexible reaming device that consists of a series of disposable tube assemblies, disposable reamer heads and reusable drive shafts. The device is designed for expedited reaming of the medullary canal in preparation for internal fixation. The free-rotating reamer head attaches to the distal end of the tube assembly. Ports in the manifold of the tube assembly allow simultaneous irrigation and aspiration through the tube assembly during the reaming process. Irrigating fluid is passed through the cannula of the drive shaft and reamer head and aspiration is drawn through ports of the retainer and aspiration tube. The RIA device is available in reaming diameters ranging from 10 to 19 mm and effective reaming lengths ranging from 200 to 580 mm.
Intended Use:	Synthes RIA System is intended to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2002

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
P. O. Box 1766
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K013527
Trade Name: Synthes Reamer Irrigator Aspirator (RIA) System
Regulation Number: 888.4540, 888.1100
Regulation Name: Orthopedic manual surgical instrument
Arthroscope and Accessories
Regulatory Class: II
Product Code: HTO, HRX
Dated: November 29, 2001
Received: November 30, 2001

Dear Ms. Smith:

This letter corrects our substantially equivalent letter of December 21, 2001, regarding the regulation number and product code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2. Indications for Use

Special 510(k) Device Modification

INTENDED USE STATEMENT

510(k) Number (if known): K013527

Device Name: Synthes Reamer Irrigator Aspirator (RIA) System

Indications

Synthes RIA System is intended to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013527